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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,062	03/11/2004	Dan-Hui Dorothy Yang	10030934-1	5691

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AGILENT TECHNOLOGIES, INC.
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EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,062	YANG ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 5-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-11 are pending.

Claims 1, 2, and 5-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention (methods for detecting a biopolymer), there being no allowable generic or linking claim.

Claims 3 and 4 are examined on the merits.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, and 5-11, drawn to a method for detecting a biopolymer comprising a metal-labeled biopolymer, a nanopore, and a detectable signal produced by a voltage, classified in class 435, subclass 6.
 - II. Claims 3 and 4, drawn to an apparatus comprising a nanopore in a substrate, classified in class 435, subclass 286.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of group II (an apparatus that is a nanopore in a substrate) can be used for methods other than detecting the presence of a biopolymer. For example, the apparatus of group II (a nanopore in a substrate) could be used in a drug delivery system, or for the transport of nanoparticles.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I and II require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. During a telephone conversation with Timothy Joyce on 08/30/2006 a provisional election was made **with traverse** to prosecute the invention of Group II, claims 3 and 4,

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drawn to an apparatus. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 2, and 5-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement; see for example page 1 lines 19-20 and page 3 lines 17-18. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

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6. Claims 3 and 4 are objected to because a claim to a product does not properly depend from a claim to a method in which that product may be used. As stated in MPEP 608.01(n):

The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim.

On the other hand, if claim 1 recites a method of making a specified product, a claim to the product set forth in claim 1 would not be a proper dependent claim since it is conceivable that the product claim can be infringed without infringing the base method claim if the product can be made by a method other than that recited in the base method claim.

In the present situation, the apparatus of claim 3 and 4 do not include every limitation of the claim from which they depend (i.e. claim 1) because claims 3 and 4 do not require performing the method steps recited in claim 1.

Claim 4 is objected to because the claim recites the phrase 'wherein biopolymer is' where the phrase 'wherein said biopolymer is' is likely intended.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 3 and 4 are drawn to an apparatus as recited in claim 1 with the further limitations 'wherein said biopolymer is conductive' (claim 3) and 'wherein biopolymer is double stranded oligonucleotide' (claim 4). It is unclear if applicant intends that a positioned biopolymer is in fact part of the apparatus that is a nanopore in a substrate, or if the apparatus is in some way associated with the biopolymer.

Claim Rejections - 35 USC § 102

Claims 3 and 4 are each drawn to 'an apparatus as recited in claim 1', and have further limitations regarding the 'biopolymer'. However, the biopolymer is not required for the apparatus of claim 1, which is 'a nanopore in a substrate'.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Branton et al (2000) Publication WO 00/079257 A1.

Branton et al teaches methods and apparatus for the evaluation of biopolymers. The reference teaches an apparatus comprising nanopores (termed in the reference as

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nanoscale apertures of holes) in a substrate, and provides examples of suitable substrates such as silica (see for example p.13, Ins.5-11).

11. Claims 3 and 4 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Su, Pub No.: US 2003/0232346 A1 (published 12/18/2003, filed 6/17/2002).

The rejection of claims is made under 102(a) based on the publication date of the applied reference (the publication date is 12/18/2003) and under 102(e) based on the filing date of the applied reference (6/17/2002).

Regarding claims 3 and 4, Su teaches methods and apparatus for the analysis of nucleic acid sequences. The reference teaches the analysis of labeled nucleic acids using an apparatus comprising a nanopore in a substrate, and provides examples such as alpha-hemolysin in a lipid bilayer (paragraph [0054]) and nanopores constructed in silicon (paragraph[0056]).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 13-20, and 25-27 of copending Application No. 10/352,675. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are drawn to an apparatus comprising a substrate with a nanopore.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 and 30-53 of copending Application No. 10/821,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are drawn to an apparatus comprising a substrate with a nanopore.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 13-19 of copending Application No. 10/957,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are drawn to an apparatus comprising a substrate with a nanopore.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 13-19 of copending Application No. 10/996,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are drawn to an apparatus comprising a substrate with a nanopore.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/898,586. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are drawn to an apparatus comprising a substrate with a nanopore.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 13-19 of copending Application No. 10/971,475. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are drawn to an apparatus comprising a substrate with a nanopore.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634


CARLA J. MYERS
PRIMARY EXAMINER